

Transmittal Letter to the United States  
Designated/Elected Office (DO/EO/US)

09/831996 .013102 Page 1

FORM PTO-1390

JC17 Rec'd PCT/PTO 16 MAY 2001

09/831996

Docket No. **MR-25PCT**  
U.S. Application No.  
International Application No.: **PCT/EP99/08602**  
International Filing Date : **NOVEMBER 10, 1999**  
Priority Dates Claimed **NOVEMBER 17, 1998 and MARCH 5, 1999**  
Title of Invention **NAVIGATION SYSTEM FOR PERFORMING AND ASSISTING SURGICAL OPERATIONS, MARKING DEVICE OR FIDUCIAL, AND POINTER FOR A TRACKING DEVICE IN A NAVIGATION SYSTEM**  
Applicant(s) for (DO/EO/US) **Thomas Hoell, Udo Warschewske and Hans-Martin von Stockhausen**

Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:

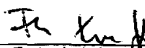
1. ☒ This is a **FIRST** submission of items concerning a filing under 35 U.S.C. 371
2. ☐ This is a **SECOND** or **SUBSEQUENT** submission of items concerning a filing under 35 U.S.C. 371
3. ☒ This express request to begin national examination procedures 35 U.S.C. 371 (f) at any time rather than delay examination until the expiration of the applicable time limit set forth in 35 U.S.C. 371(b) and PCT Articles 22 and 39(1)
4. ☐ A proper Demand for International Preliminary Examination was made by the 19th month from the earliest claimed priority date
5. ☒ A copy of the International Application as filed [35 U.S.C. 371(c)(2)].
  - a) ☒ is transmitted herewith (required only if not transmitted by the International Bureau).
  - b) ☐ has been transmitted by the international Bureau.
  - c) ☐ is not required, as the application was filed in the United States Receiving Office (RO/US)
6. ☒ A translation of the International Application into English [35 U.S.C. 371(c)(2)]
7. ☐ Amendments to the claims of the International Application under PCT Article 19 [35 U.S.C. 371(c)(3)]
  - a) ☐ are transmitted herewith (required only if not transmitted by the International Bureau)
  - b) ☐ have been transmitted by the International Bureau.
  - c) ☐ have not been made, however, the time limit for making such amendments has **NOT** expired
  - d) ☐ have not been made and will not be made
8. ☐ A translation of the amendments to the claims under PCT Article 19 [35 U.S.C. 371(c)(3)].
9. ☒ An oath or declaration of the inventor(s) [35 U.S.C. 371(c)(4)] **UNSIGNED**
10. ☐ A translation of the annexes to the International Preliminary Examination Report under PCT Article 36 [35 U.S.C. 371(c)(5)]

Items 11. to 16. below concern other document(s) or information included:

11. ☐ An Information Disclosure Statement under 37 C.F.R. 1.97 and 1.98.
12. ☐ An Assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included
13. ☐ A **FIRST** preliminary amendment  
☐ A **SECOND** or **SUBSEQUENT** preliminary amendment
14. ☐ A substitute specification
15. ☐ A change of power of attorney and/or address letter.
16. ☒ (other items or information) **Nine sheets of drawings**

EXPRESS MAIL No : EL 803 955 729 US Deposited May 16, 2001

I hereby certify that this correspondence is being deposited with the United States Postal Service Express mail under 37 CFR 1.10 on the date indicated above and is addressed to the Commissioner of Patents and Trademarks, Washington, DC 20231.

  
Friedrich Kueffner

May 16, 2001  
Date

09/831996

U.S. Application No. (if known, see 37 C.F.R. 1.50).  
 International Application No. PCT/EP99/08602

Page 2  
 Docket No. MR-25PCT  
 JC18 Rec'd PCT/PTO 1 6 MAY 2001

17. ☒ The following fees are submitted:

**BASIC NATIONAL FEE [37 CFR 1.492(a)(1)-(5)]:**

- ☒ Search Report has been prepared by the EPO or JPO. . . . . \$ 860.00
- ☐ International preliminary examination fee paid to USPTO [37 CFR 1.482] . . . . . \$ 690.00
- ☐ No International preliminary examination fee paid to USPTO [37 CFR 1.482] but International search fee paid to USPTO [37CFR 1.445(a)(2)] . . . . . \$ 710.00
- ☐ Neither International preliminary examination fee [37 CFR 1.482] nor International search fee [37 CFR 1.445(a)(2)] paid to USPTO . . . . . \$ 1000.00
- ☐ International preliminary examination fee paid to USPTO [37 CFR 1.482] and all claims satisfied provisions of PCT Article 33 (2) to (4) . . . . . \$ 100.00

ENTER APPROPRIATE BASIC FEE AMOUNT: \$ 860.00

Surcharge of \$ 130.00 for furnishing the oath or declaration later than 20 30 months from the earliest claimed priority date [37 CFR 1.492(e)]

Claims	filed	Extra	Rate	
Total Claims	22	-20=	2	x \$ 18 =
Indep. Claims	3	-3=		x \$ 80. =
(X) Multiple Dependent Claims (if applicable) + \$ 270. =				\$ 270.00

TOTAL OF ABOVE CALCULATIONS: \$1166.00

Reduction by  $\frac{1}{2}$  for filing by small entity, if applicable. Verified Small Entity Statement must be filed also [Note 37 CFR 1.9, 1.27, 1.28]

(divided by 2)

SUBTOTAL: \$1166.00

Processing fee of \$ 130.00 for furnishing the English translation later than 20 30 months from the earliest claimed priority date [37 CFR 1.492(f)]

TOTAL NATIONAL FEE: \$1166.00

Fee for recording the enclosed assignment [37 CFR 1.21(h)] the assignment must be accompanied by an appropriate cover sheet [37 CFR 3.28, 3.31] \$ 40.00 per property

TOTAL FEES ENCLOSED: \$1166.00

AMOUNT TO BE REFUNDED: Refunded \$

AMOUNT TO BE CHARGED: Charged \$

- a) ☒ A check in the amount of \$1,166.00 to cover the above fees is enclosed
- b) ☐ Please charge my Deposit Account No. 11-1835 in the amount of \$ to cover the above fees. A duplicate copy of this sheet is enclosed.
- c) ☒ The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 11-1835. A duplicate copy of this sheet is enclosed.

NOTE: Where an appropriate time limit under 36 CFR 1.494 or 1.495 has not been met, a petition to revive [37 CFR 1.137(a) or (b)] must be filed and granted to restore the application to pending status

SEND ALL CORRESPONDENCE TO:

Friedrich Kueffner  
 342 Madison Avenue  
 Suite 1921  
 New York, NY 10173

Friedrich Kueffner  
 Name

*F. Kueffner*  
 signature

29,482  
 Reg. No.

May 16, 2001  
 Date

**PCT**  
 WELTORGANISATION FÜR GEISTIGES EIGENTUM  
 Internationales Büro  
 INTERNATIONALE ANMELDUNG VERÖFFENTLICHT NACH DEM VERTRAG ÜBER DIE  
 INTERNATIONALE ZUSAMMENARBEIT AUF DEM GEBIET DES PATENTWESENS (PCT)

0943 1106 013102

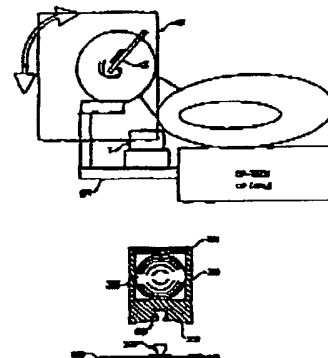
(51) Internationale Patentklassifikation 7 : <b>A61B 19/00</b>	<b>A1</b>	(11) Internationale Veröffentlichungsnummer: <b>WO 00/28911</b>  (43) Internationales Veröffentlichungsdatum: <b>25. Mai 2000 (25.05.00)</b>		
<table style="width: 100%;"> <tr> <td style="width: 50%; vertical-align: top;">           (21) Internationales Aktenzeichen: <b>PCT/EP99/08602</b>             (22) Internationales Anmeldedatum: <b>10. November 1999 (10.11.99)</b>             (30) Prioritätsdaten:                198 53 010.2      17. November 1998 (17.11.98)    DE                199 09 816.6      5. März 1999 (05.03.99)      DE             (71) Anmelder (für alle Bestimmungsstaaten ausser US): <b>NICOLET BIOMEDICAL INC. (US/US); 5225-2 Verona Road, Madison, WI 53711-4495 (US).</b>             (72) Erfinder; und            (75) Erfinder/Anmelder (nur für US): <b>HOELL, Thomas (DE/DE); Liebenauerstrasse 16, D-06110 Halle/Saale (DE); WARSCHIEWSKE, Udo (DE/DE); Dessauerstrasse 13, D-12249 Berlin (DE); VON STOCKHAUSEN, Hans-Martin (DE/DE); Hindenburgstrasse 69, D-91054 Erlangen (DE).</b>             (74) Anwälte: <b>KRUSPIG, Volkmar usw.; Meissner, Bolte &amp; Partner, Postfach 86 06 24, D-81633 München (DE).</b> </td> <td style="width: 50%; vertical-align: top;">           (81) Bestimmungsstaaten: <b>AE, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CU, CZ, DE, DK, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, UA, UG, US, UZ, VN, YU, ZA, ZW, ARIPO Patent (GH, GM, KE, LS, MW, SD, SL, SZ, TZ, UG, ZW), eurasisches Patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), europäisches Patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI Patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).</b>   <b>Veröffentlicht</b>  <i>Mit internationalem Recherchenbericht</i>  <i>Vor Ablauf der für Änderungen der Ansprüche zugelassenen Frist; Veröffentlichung wird wiederholt falls Änderungen eintreffen.</i> </td> </tr> </table>			(21) Internationales Aktenzeichen: <b>PCT/EP99/08602</b>  (22) Internationales Anmeldedatum: <b>10. November 1999 (10.11.99)</b>  (30) Prioritätsdaten: 198 53 010.2      17. November 1998 (17.11.98)    DE 199 09 816.6      5. März 1999 (05.03.99)      DE  (71) Anmelder (für alle Bestimmungsstaaten ausser US): <b>NICOLET BIOMEDICAL INC. (US/US); 5225-2 Verona Road, Madison, WI 53711-4495 (US).</b>  (72) Erfinder; und (75) Erfinder/Anmelder (nur für US): <b>HOELL, Thomas (DE/DE); Liebenauerstrasse 16, D-06110 Halle/Saale (DE); WARSCHIEWSKE, Udo (DE/DE); Dessauerstrasse 13, D-12249 Berlin (DE); VON STOCKHAUSEN, Hans-Martin (DE/DE); Hindenburgstrasse 69, D-91054 Erlangen (DE).</b>  (74) Anwälte: <b>KRUSPIG, Volkmar usw.; Meissner, Bolte &amp; Partner, Postfach 86 06 24, D-81633 München (DE).</b>	(81) Bestimmungsstaaten: <b>AE, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CU, CZ, DE, DK, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, UA, UG, US, UZ, VN, YU, ZA, ZW, ARIPO Patent (GH, GM, KE, LS, MW, SD, SL, SZ, TZ, UG, ZW), eurasisches Patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), europäisches Patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI Patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).</b>  <b>Veröffentlicht</b> <i>Mit internationalem Recherchenbericht</i> <i>Vor Ablauf der für Änderungen der Ansprüche zugelassenen Frist; Veröffentlichung wird wiederholt falls Änderungen eintreffen.</i>
(21) Internationales Aktenzeichen: <b>PCT/EP99/08602</b>  (22) Internationales Anmeldedatum: <b>10. November 1999 (10.11.99)</b>  (30) Prioritätsdaten: 198 53 010.2      17. November 1998 (17.11.98)    DE 199 09 816.6      5. März 1999 (05.03.99)      DE  (71) Anmelder (für alle Bestimmungsstaaten ausser US): <b>NICOLET BIOMEDICAL INC. (US/US); 5225-2 Verona Road, Madison, WI 53711-4495 (US).</b>  (72) Erfinder; und (75) Erfinder/Anmelder (nur für US): <b>HOELL, Thomas (DE/DE); Liebenauerstrasse 16, D-06110 Halle/Saale (DE); WARSCHIEWSKE, Udo (DE/DE); Dessauerstrasse 13, D-12249 Berlin (DE); VON STOCKHAUSEN, Hans-Martin (DE/DE); Hindenburgstrasse 69, D-91054 Erlangen (DE).</b>  (74) Anwälte: <b>KRUSPIG, Volkmar usw.; Meissner, Bolte &amp; Partner, Postfach 86 06 24, D-81633 München (DE).</b>	(81) Bestimmungsstaaten: <b>AE, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CU, CZ, DE, DK, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, UA, UG, US, UZ, VN, YU, ZA, ZW, ARIPO Patent (GH, GM, KE, LS, MW, SD, SL, SZ, TZ, UG, ZW), eurasisches Patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), europäisches Patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI Patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).</b>  <b>Veröffentlicht</b> <i>Mit internationalem Recherchenbericht</i> <i>Vor Ablauf der für Änderungen der Ansprüche zugelassenen Frist; Veröffentlichung wird wiederholt falls Änderungen eintreffen.</i>			

(54) Title: **SURGICAL NAVIGATION SYSTEM, MARKING DEVICE AND POINTER FOR A TRACKING DEVICE**

(54) Bezeichnung: **CHIRURGISCHES NAVIGATIONSSYSTEM, MARKIERUNGSEINRICHTUNG UND ZEIGER FÜR EINE TRACKING-EINRICHTUNG**

(57) Abstract

The present invention relates to a navigation system for carrying out and assisting surgical operations, wherein said system uses an image databank for nuclear spin and/or computer tomography data prepared for pre-operative purposes. The system includes means for extracting anatomic structures from sets of raw data previously obtained from pre-operative snapshots and for preparing said structures in the form of 3D data sets that can be visualised. The system also includes means for generating a continuous magnetic field defined within the navigation environment as well as a pointer navigation instrument with an integral magnetic field detector, wherein the magnetic field detector and the continuous field emitter represent the tracking device. The system also includes a menu-guided control, wherein movements of the pointer navigation instrument outside the surgical site but within the navigation environment, i.e. within the control field, activate or deactivate the proposed menus or control activities. The present invention also relates to a special marking device or fiducial represented during the generation of image data and used for detecting the position of a volunteer as well as for assigning co-ordinates during surgical operations. This invention further relates to a pointer for the tracking device of the navigation system, comprising a detector specially mounted in a housing connected with a contact tip.



9/PRTS

5

Navigation system for performing and assisting surgical  
operations, marking device or fiducial, and pointer for a  
tracking device in a navigation system

10

DESCRIPTION

15 The invention relates to a navigation system for performing and  
assisting surgical operations, in particular in the area of  
neurosurgery and ear-nose-throat medicine, to a marking device  
or fiducial for producing image data for a database by means of  
nuclear-spin and/or computer tomography and for detecting the  
20 position of a test subject and assigning coordinates for  
surgical operations assisted by a navigation system, and to a  
pointer for a tracking device in a navigation system.

25 Neuro-navigation systems provide assistance during surgical  
operations on the skull. Known navigation systems enable the  
position of a surgical instrument within the operation field to  
be indicated, so that small, deep-seated lesions in the brain  
can be reliably targeted in an atraumatic manner. During  
operations in the area of ENT medicine, for example, a  
navigation system can be used to distinguish reliably between  
the boundaries of the paranasal sinuses and the brain.

30 Navigation systems that operate with various tracking methods  
are known. For example, reference is made here to the  
StealthStation system made by Sofamor Danek Inc, USA. With the  
known systems the first step is to obtain a preoperative image  
of the anatomy or the brain of the subject or patient. Then a  
35 tracking system with optical sensor can be used to display

slices or views of the brain on a monitor, on the basis of the image data obtained preoperatively. During the preoperative scanning by means of computer and/or nuclear-spin tomography so-called fiducial markers are attached to the surface of the patient's head. These fiducials serve to identify the location of the images, taking into account the spatial orientation in each case.

The use of known systems is restricted by an elaborate structure of the equipment and by the fact that they are complicated and time-consuming to operate, especially during optical tracking.

Tracking methods are also known that rely on alternating magnetic fields to detect the position of a pointer for the imaging system; these are not well suited for use in surroundings that produce magnetic interference, as is routinely the case in the clinical context.

Further disadvantages of known systems are associated with the complexity involved in requiring the operator to manipulate a computer keyboard as well as the pointer, in order to record the image or to carry out controlling or marking procedures.

In the case in which optical sensors or optical tracking are employed, elaborate calibrations must be performed, in particular when the operating table bearing the patient is moved in space, so that undesired changes in position of the optical sensor system are produced. To overcome such problems an optical reference system is attached to the skull, or to the head-holder that is fixed to the skull. Although this does overcome the calibration problem, the reference markers are so large and susceptible to mechanical alteration that they have a disturbing effect during the operation.

Previously known fiducials, i.e. marking devices for producing image data by means of nuclear-spin and/or computer tomography

5

10

20

30

preoperatively attached marking device must remain in place until the operation has been performed.

Finally, the invention is intended to provide a pointer or stylus for a tracking device of a navigation system for  
5 carrying out and assisting surgical operations on the basis of an elongated handpiece housing, such that the pointer should satisfy all of the clinical requirements and be resistant to the mechanical-thermal stresses of sterilization.

These objectives are achieved with respect to the navigation  
10 system by the definition according to the teaching of Claim 1; with respect to the marking device or fiducial with an object according to the characteristics given in Claim 8; and regarding the pointer for a tracking device of a navigation system by a combination of characteristics such as is disclosed  
15 in Claim 13.

The subordinate claims represent at least advantageous embodiments and further developments of the respective subject matter or of the system.

The basic idea of the invention regarding the navigation system  
20 for carrying out and assisting surgical operations consists in the further development of known solutions in such a way that to implement the tracking device for detecting the momentary position of an instrument and deriving or redrawing in real time representations of the patient's anatomy on the basis of  
25 images stored in an image databank, means are employed to generate a specified constant magnetic field in the navigation environment, so that a pointer navigation instrument is used that comprises an integral magnetic-field sensor tuned to the constant magnetic field of the transmitter.

30 The invention further provides a software module by means of which anatomical structures are extracted from the sets of raw

- 5 -

data derived from the preoperative images and these structures are made available in the form of visualizable 3D data sets.

By the above-mentioned image-processing module anatomical structures can be selected according to their properties or  
5 surroundings from the complete input data sets obtained preoperatively, and can be converted into discrete data sets on the basis of a predeterminable segmentation strategy.

Another basic idea of the navigation system in accordance with the invention is to employ means that permit menu-guided  
10 control of the system by movement of the pointer navigation instrument outside the operation field but within a navigation environment, such that activation or deactivation of displayed menus or control functions can be accomplished entirely by the previously mentioned movement of the navigation instrument.

15 The special constant-field transmitter to generate a magnetic field for the tracking device is disposed at the operating table or a head-support provided there, so that it is stably positioned with respect to the subject but is outside the operation field and hence causes no interference. As a result,  
20 the transmitter is in a spatially fixed, reproducible relation to the subject, who is fixed to or on the operating table, in particular to or on a head-support, regardless of the spatial position of the operating table itself.

The magnetic-field sensor makes available signals for recording  
25 position and/or direction of movement of the pointer navigation instrument on the basis of the specified constant magnetic field and its orientation, such that these signals can be displayed on a monitor and also used to control reloading and updating by the image-processing module.

30 In a preferred embodiment of the invention an additional magnetic-field sensor is provided, which can be attached to the subject, preferably cranially (i.e. to the skull) or to another



- 6 -

part of the body to be navigated. As a result, changes in location and orientation of the skull or other part of the body with respect to the constant-field transmitter can be detected. By means of this additional sensor, positional alterations that otherwise would necessitate new initializing measurements or adjustments of the system are correlated or compensated automatically within the system. In this case, if the surgical technique requires it, the operator can change the position of the skull as desired, with no limitation imposed on the navigation owing to a lack of adjustment or the need for readjustment. In other words, the additional magnetic-field sensor makes available corrective data that are sent to the control computer to determine a quasi-dynamic or alterable (with reference to the source alteration) coordinate system.

Using the system briefly described above, the surgeon or system operator has considerably less work to do and the number of possible sources of error during the operation is reduced. This is made possible in particular by the virtual control panel, by means of which the surgeon can make use of and control all the essential functions of the navigation system and the computer implemented there, with no help from anyone else. In detail, it is possible to change the forms of representation and the views of the anatomical structures and/or to turn on specific functions. For this purpose an easily surveyed menu on the monitor or display is used, such that activation or deactivation is achieved by the above-mentioned simple spatial movement of the navigation instrument outside the operation field.

The use of a tracking system based on measurement of the field strength of constant magnetic fields effectively suppresses signal distortions caused by electromagnetically induced field superposition. The components of the navigation system, in particular the constant-field transmitter, can be disposed beneath sterile operation-field coverings, so that the surgeon's field of view and its immediate surroundings are not

- 7 -

restricted, and there is no interference with the surgical procedure. In comparison to optical navigation systems, the solution in accordance with the invention is structurally insensitive to mechanical impacts. Furthermore, the patient can  
5 be freely moved in space along with the operating table, without navigational restriction. The automated image processing in the present system substantially shortens the preparation times, and the 3D representation of the brain on the monitor and the view of the brain obtained after craniotomy  
10 are identical, so that the surgeon has more opportunity to plan the operation before it is begun.

In order to use the navigation system, the head of the patient is fixed in position by the neurosurgeon prior to the operation in the manner known per se, employing the appropriate  
15 mechanical head supports. The head-support system can be made of conventional materials such as aluminium or high-alloy steel, with no risk of interference with the tracking device. By means of the navigation system the patient's head position is recorded during the initializing measurements, and at first  
20 an image perspective from the viewpoint of the surgeon is presented automatically as a 3D graphic. The position of the operating table itself has no influence on the navigation process, because the head-holder and the transmitter of the tracking device are in a fixed orientation with respect to one  
25 another.

For preferred neurosurgical application, as described, first the 3D picture of the brain is presented as it appears to the surgeon at the beginning of the operation. However, this perspective can be altered at any time by means of the  
30 navigation instrument, i.e. the pointer, which will be described later.

In one embodiment of the invention the navigation system has the supplementary function of enabling electrophysiological measurements to be documented. For this purpose, the monitor

For navigation, as is generally known, it is necessary to create a registration between the virtual image of the brain and the real brain of the patient lying on the operating table in theatre. For this purpose unambiguous reference points are needed, which can be found again in both the real and the virtual system. Fundamentally anatomical landmarks are used, although owing to displacements of the skin and to the size of the landmarks it is not always possible to achieve great precision.

Some known marker systems that conform to the precision required, and take into account the possibility of skin displacement, are fixed in position by screwing them to the skull bone. Alternatives consist in using mouthpieces on which the patient must bite during the tomographic examination as well as in the operating theatre. Such methods are associated with a large financial and temporal expenditure and are extremely unpleasant for the patient. Markers generally can be screwed in only by a physician because of the invasive nature of this treatment, which further increases the costs.

- 9 -

Hence according to a supplementary basic idea of the invention, a special marking device or fiducial was created for producing image data for a database by tomography on one hand, and on the other hand also for monitoring the position of a subject and  
5 assigning coordinates for the surgical operation.

In accordance with the invention a carrier is present in the form of a flat, at least partially flexible structure with a catch knob substantially centred on the side away from the adhesive surface.

- 10 The actual marking substance is contained in a substantially cylindrical housing that can easily be handled. The underside of the housing preferably has a concave form or is recessed, and on this underside is disposed a substantially centred catch receptacle or a counterpart to the catch knob.
- 15 The catch knob on one hand and the receptacle or counterpart on the other hand make it possible to attach the cylindrical housing after the carrier has been fixed to the subject, or to release the housing at a later time and reattach it. Thus the patient can have the relatively large-volume cylindrical
- 20 housing containing the marking substance removed after, or in an interval during, the tomography and move about unimpeded. Then for continuing the tomography and for the subsequent operation, the cylindrical housings can be attached again in exactly the same position, or special accessories for the
- 25 initializaing measurement can be attached in the operating theatre by making use of the catch knob.

- The selected adhesive coating in combination with the concave or recessed shape of the housing floor, the curvature of which corresponds approximately to that of the skull, ensures that
- 30 the filmlike carrier or the adhesive plate is pulled close to the plastic element, i.e. the housing for the marking substance. This feature makes it possible for the distance between marking substance, which is contained for instance in a

- 10 -

spherical housing, and the skin surface to be kept the same even for different radii of curvature, i.e. over different parts of the skull. Ultimately it also avoids errors in the initialization measurement, because the dimensions of the  
5 initialization element, in particular with respect to the concave or recessed configuration of the underside, correspond to those of the cylindrical body with marking substance or to a receptacle therefor.

10 In one embodiment the cylindrical housing for the marking device comprises a removable housing lid, preferably made of a transparent plastic, so that the marking substance can be monitored and is also exchangeable.

The marking substance for nuclear-spin tomography is a liquid or a gel that is held in a spherical or closed cylindrical  
15 container, such that the outside diameter of the sphere or cylinder corresponds substantially to the inside diameter of the cylindrical housing with catch receptacle or counterpart. The substance to be used is selected such that it is easily visible in the nuclear-spin as well as in the T1 and also the  
20 T2-weighted image. The special feature in comparison to known markers is that the latter are ordinarily easily visible only in the T1 or T2 image. At the same time, the marking can be well discerned in computer tomography by way of the difference in contrast between the sphere and the housing. As a result,  
25 even if the wrong marking aid is selected, any desired marking chosen by the user can be discerned on the CT or X-ray images with relatively little difficulty. This feature serves to eliminate the need to remeasure the patient in case the wrong marking aid is chosen and, in particular in cases of CT  
30 marking, to prevent extra radiation exposure.

It should be noted at this juncture that of course a kinematic reversal of catch knob and receptacle or counterpart is conceivable without departing from the principle in accordance

- 11 -

with the invention, namely the separation of the carrier from the cylindrical container of the actual marking substance.

As described briefly above, in accordance with the invention a initialization element is provided that has a closed shape  
5 corresponding in its dimensions and the configuration of its underside to the cylindrical housing. This element comprises on its lid side a marking depression located in a position that is the same as the middle or centre of gravity of the contrast marking substance, i.e. of the spherical or cylindrical  
10 container for such a substance. This marking aperture can be contacted with a pointer or stylus to facilitate the initialization measurement.

Preferably the cylindrical housing to contain the marking substance and/or the initialization element consists of a  
15 plastic material, and the carrier preferably comprises an adhesive-coated film reinforced on one side in the region of the catch knob.

Specifically for use in the described navigation system a pointer is proposed for the necessary tracking device, such  
20 that the pointer has the shape of an elongated handpiece housing within which a preferably encapsulated sensor is present, and at least partially projecting from the housing there is a contact tip or a receptacle for a contact tip or insertion accessory.

25 In accordance with the invention the encapsulated sensor is rigidly connected to the contact tip or the contact-tip receptacle by means of an element with openings on opposite sides.

The connecting element with sensor and contact tip situated in  
30 the respective openings is then mounted so as to be yielding with respect to the handpiece housing, i.e. the mounting is stress-free and quasi-cardanic.

5

10

25

30

The contact tip of the pointer is made of a rigid material, preferably stainless steel or titanium. Alternatively, the above-mentioned tip receptacle can also be used to attach

- 13 -

puncture accessories or accessories for the introduction of catheters and so on. Common to all inserted tips is that they have a point directed towards the object to be investigated, which serves as a reference point for navigation. The reference point itself can be freely chosen. This feature is made possible by the fact that the sensor for the navigation system that is situated in the pointer measures with respect to the specified virtual centre, independently of the system itself. The tip of the pointer is defined by a vector that is calculated with reference to the specified position of the sensor. To determine this vector the initialization procedure mentioned above is needed. In concrete terms, the pointer is moved about its tip at a fixed position, e.g. by means of the initialization element. The navigation system detects this movement with the aid of the tracking device and calculates, on the basis of the known position of the tip, how the tip of the system behaves with reference to the location of the sensor.

The pointer for the tracking device of the navigation system in accordance with the invention is largely liquid- and vapor-tight, so that it can be sterilized by conventional clinical means. The provision of the connecting element and its disposition in the elongated housing ensure that even under mechanical stress and/or during temperature changes the relative positions of sensor and tip remain unchanged, so as to achieve the required precision of position monitoring and navigation.

In the following the invention is explained with reference to exemplary embodiments, the description of which is assisted by figures, wherein

Fig. 1 shows the principles of carrying out an image-assisted navigation procedure;

Fig. 2 shows the arrangement of a transmitter of the tracking device on the operating table;



- 14 -

- Fig. 3 shows the arrangement of an additional sensor for detecting the patient's head movement;
- Fig. 4 shows the organization of operation field and virtual control field for operating the system by means of pointer or stylus;
- Fig. 5 shows a monitor display with the menu for marker recording;
- Fig. 6 shows a monitor display with the menu for checking the markers or fiducials;
- Fig. 7 shows a monitor display with virtual keypad;
- Fig. 8 shows a display including the field for initiating and carrying out intraoperative documentation;
- Fig. 9 is a sectional drawing of the separable marking device;
- Fig. 10 is a perspective drawing of the complete marking device;
- Fig. 11 is a perspective drawing of the carrier for the marking device, but with initialization element attached; and
- Fig. 12 is a sectional drawing of the pointer or stylus for the tracking device.

The navigation system according to the exemplary embodiment requires the most accurate possible image data representing the patient's anatomical structures. As shown in Fig. 1, these image data are made available by either computer tomography and/or nuclear-spin tomography.

- 15 -

Computer-tomographic representations are advantageous when bony structures are to be visualized. To represent soft parts such as the brain, nuclear-spin tomography is preferred. For taking the pictures and for subsequent monitoring of position, so-called markers are placed on the patient's head. The markers comprise a liquid or a gel which, depending on the particular tomographic method being used, ensures sufficient contrast in the image that the markers can be identified.

After the data have been transferred by way of a local network or suitable storage media, the scanned images are further processed by an automated system with the aim of obtaining the most authentic possible 3D representation of the brain, to which the surgeon can refer before the operation so as to plan ahead and design a minimally invasive procedure. By means of segmentation steps, mathematical methods are applied to enable particular anatomical structures to be extracted from the complete data sets.

For neuro-navigation it is then necessary to create a registration between the virtual image of the brain, obtained from the scanned data, and the real brain in the operating theatre.

For this purpose unambiguous positions must be established that can be found again in both the real and the virtual system. In order to determine the locations of these sites, additional markers are used to serve as reference points. The markers are situated in the same environment as those that had been used for the MR or CT scanning. Regarding the structure and utilization of the markers according to the exemplary embodiment, see the description of Figs. 9 to 11 below.

For detecting position the navigation system according to the exemplary embodiment comprises a constant-magnetic-field transmitter T, which is connected to the operating table OPT. As shown in Fig. 2, the patient's head can be fixed in place by

In another exemplary embodiment, illustrated by Fig. 3, an additional sensor is attached to the patient's head; this sensor, called the head sensor KS, is provided so that in case the head is not rigidly fixed, its movements can be detected automatically, eliminating the need for manual calibration following each change in position. The corrective data provided by the head sensor are sent to a control computer (not shown) in order to establish a coordinate system that is quasi-dynamic, or alterable with reference to the source alteration, without impairing the properties of their navigation system, i.e. the precise registration between virtual image and real appearance.

Figure 4 is intended to show how the menus shown in Figs. 5 to 8 can be activated, and control commands initiated, without any input aids apart from the pointer or stylus described below, in that the operation field OF and control field SF are separate from one another and the pointer or stylus is moved inward or outward with respect to these fields.

The relevant switching process involves recognition that a spatial distance or boundary has been crossed. This occurs when the sensor within the pointer, which detects the magnetic field emitted by the transmitter, is situated in or at this boundary region. Appropriate control commands can be triggered or confirmed by an electronic switching element, such as a key, disposed in the pointer housing.

- 17 -

Figure 5 is a hard copy of the navigation screen, i.e. a monitor display, at a time when the procedure is in the stage of recording the markers. As can be seen from the monitor display, up to six (for example) markers are usable, so that a  
5 generally high degree of reproducibility is obtained even if a marker becomes detached or must be removed during preparation for surgery. In principle an arbitrarily large number of markers can be used, but an optimal number is 4 or 5.

Figures 6 to 8 show other pictures of the navigation screen to  
10 demonstrate so-called fiducial management, the virtual keypad to control the navigation system, and the possibility of intraoperative documentation for subsequent analysis or evaluation of the treatment. With respect to the initialization measurement by means of the initialization elements shown in  
15 Fig. 11, it should be noted that this step has the purpose of creating a predetermined spatial (i.e., defined by coordinates) relation of the patient's head to its virtual image displayed on the monitor. To this end, the initialization elements are stuck onto the special carriers that have already been disposed  
20 on the patient's skin. These elements, as explained below, comprise depressions that are contacted in arbitrary sequence by the contact tip of the pointer or stylus. That each such position has been reached is confirmed by actuating the above-mentioned key disposed on the pointer. The position itself is  
25 recorded by the navigation computer as a result of automatic detection of the location of the sensor disposed in the pointer, and is indicated by the lighting of a switch symbol in the display. After all positions have been recorded, the navigation system is ready for use; in the case of  
30 neurosurgical applications, the system is preset in such a way that the 3D image of the brain is first shown from the viewpoint of the surgeon. It is of course possible at any time, by means of the pointer and the function VIEW on the virtual menu, to change this direction of view.

- 18 -

The above-mentioned markers can be removed from the patient's head before surgery is begun, so that they cannot interfere with the procedure.

5 The marking devices or fiducials for the proposed navigation system will now be explained further with reference to Figs. 9 to 11.

10 The marking units to be inserted are attached to the relevant object, for instance the human skull, and the contrast substances present in them allow them to be displayed as a group by the imaging procedure currently in use. Independently of this procedure, the position of these marking units can be discerned at a later time, namely in the operating theatre. By comparing and combining the positional data regarding these units that were obtained during the imaging procedure, i.e. are  
15 contained in the image data sets, and those that are seen in reality, the coordinates can be matched to one another. This in turn is the basis for the assignment of arbitrary points to places in the coordinate system, so that an appropriate navigation becomes possible.

20 Figure 9 shows a cross-section through the special, separable marking device. A carrier 600 attached to the subject is preferably made of a piece of plastic film with an adhesive coating on one side. Accordingly, the carrier 600 is constructed as a flat sheet, preferably in a circular shape.  
25 The carrier can be variously designed; for instance, it can have a large adhesive surface for adults and a small one for children, and the adhesive in the coatings can be different to suit differentially sensitive skin types. In the exemplary embodiment the catch knob is made of carbon, which offers the  
30 advantage that while being mechanically stable, it does not produce an artefact in either nuclear-spin or computer tomography.

- 19 -

On the side of the carrier 600 facing away from the adhesive surface, there is a projecting catch knob 500. This catch knob 500 serves for attachment of a cylindrical housing 200, which on its underside comprises a catch receptacle or counterpart  
5 400. The underside 700 of the cylindrical housing 200 has a concave shape or is recessed correspondingly.

By means of the catch knob 500 and catch receptacle 400 the cylindrical housing can be connected to the carrier 600, which has already been attached to the patient. After the images have  
10 been obtained, i.e. after the tomography scanning has been completed, the cylindrical body or housing 200, which is easily handled because it projects outward, is removed from the patient. Then in the operating theatre it can be replaced by the initialization element 900 shown in Fig. 11, in order to  
15 carry out the initialization measurement.

As can be seen in Fig. 9, the cylindrical housing 200 comprises an opening that serves to receive a sphere 300, in the interior of which is contained a contrast liquid or gel to be used for nuclear-spin or computer tomography.

20 The cylindrical housing 200 is closed by a lid 100 that can be removed by a tool and that is preferably made of a transparent plastic material. Because of its transparency, by looking through the lid 100 it is possible to see how much marking liquid remains in the sphere 300. The sphere 300 containing the  
25 marking substance can also be exchanged for another suitable container. The fiducials are basically complete structures, which contain spheres that are optimal for the particular imaging technique to be used in each case.

The shape of the underside 700 enables variation in the  
30 curvature of objects such as the human skull to be compensated, so that the seating of the marking device does not need to be changed and does not become unstable. Furthermore, this underside 700 can accommodate the above-mentioned recess

- 20 -

serving as catch receptacle 400 or counterpart to the catch knob 500.

The material of which the carrier 600 with its adhesive surface is composed has a flexibility matched to that of the skin and  
5 can conform to the surface of the body; nevertheless, it is resistant to distortion of its basic shape, so that the catch knob 500 is always situated in the same place, preferably the middle of the carrier 600, as is required for precise marking. The opening in the cylindrical housing 200 of the marking  
10 device is so constructed that the sphere containing the marking substance is held reliably and quasi-immovably in place, i.e. is stably positioned.

Figure 10 shows the complete marking device, i.e. the carrier  
600 onto which has been set the cylindrical housing 200 with  
15 lid 100.

After the tomography images have been obtained, the cylindrical housing 200 with sphere 300 containing the contrast-marking substance is removed from the carrier 600 by operating the releasable connection, and the patient can then move without  
20 hindrance. Because the carrier film remains on the patient, i.e. the carrier 600 with catch knob 500 is still adhering, it is possible to carry out the desired initializing measurement preoperatively with exact assignment of positions. For this process the accessory shown in Fig. 11, in the form of an  
25 initialization element 900, is set onto the carrier. The initialization element preferably consists of a solid plastic body, the crucial feature of which is a depression 800 at its centre that corresponds in position precisely to the midpoint or centre of gravity of the sphere 300 that contains the  
30 marking substance. This ensures that during initialization with the pointer or stylus, the virtual and the real spherical centre of the marking device coincide. Hence after the initialization measurement, it is possible to superimpose precisely the virtual images from the navigation system and the

- 21 -

real skull. After initialization has been completed, the initialization element or the entire marker, i.e. including the carrier, can be removed from the head.

5 Regarding the design of the pointer or stylus for a tracking device associated with the navigation system presented here, reference is made to the sectional drawing shown in Fig. 12.

10 The pointer comprises a contact tip 1, or else a contact-tip receptacle that can also be used to hold various accessories. Opposite thereto is a special electromagnetic sensor 5. The sensor 5 and the contact tip 1 are fixedly connected to one another by an element 3. The element 3 in turn is mounted quasi-cardanically, i.e. is yielding and stress-free with respect to the actual handle, the elongated handpiece housing 8.

15 The connecting element 3 is preferably made of a plastic material that resists deformation and is thermostable, or of titanium.

20 In the elongated housing 8 is an opening within which is seated a key 6. The electrical output wires from the sensor 5 and from the key 6 are combined within a signal lead 7 that runs out of the handpiece.

The key 6 is fixed within the handpiece housing 8 in a vapour- and liquid-tight manner.

25 At the end of the housing 8 opposite the contact tip 1, i.e. opposite the distal end of the pointer, is situated a vapour- and liquid-tight cable outlet 9. Both the connecting element 3 and the cable outlet 9 are attached to the housing 8 in a mechanically releasable manner, by the external couplings 2, 10. To ensure a sufficiently tight seal, flexible sealing elements are provided in the region of the couplings 2 and 10, preferably in the form of sealing rings 4 and 11.

30



25 As the sensor 5 a known magnetic-field sensor is preferably  
used. Such a sensor can detect sensor position in six degrees  
of freedom, and the range of sensor movement is not restricted.  
The magnetic-field sensor detects its position, or the position  
of the contact tip 1 with respect to its own position, on the  
30 basis of a DC magnetic field present in the navigation  
environment, by appropriate real-time measurements of field  
strength.

5

10

15

List of reference symbols

	OF	Operation field
	SF	Control field
	KH	Head holder
5	T	Transmitter
	OPT	Operating table
	KS	Head sensor
	1	Contact tip
	2, 10	External coupling
10	3	Connecting element
	4, 11	Sealing rings
	5	Sensor
	6	Key
	7	Signal lead
15	8	Housing
	9	Cable outlet
	12	Annular gap
	100	Lid
	200	Cylindrical housing
20	300	Sphere with marking substance
	400	Catch receptacle
	500	Catch knob
	600	Carrier
	700	Underside
25	800	Marking recess
	900	Initialization element

# Claims

1. Navigation system for performing and assisting surgical  
5 operations, in particular in the area of neurosurgery and ear-  
nose-throat medicine,
  - wherein the system comprises an image database for  
preoperatively prepared nuclear-spin or computer tomography  
(CT or MR) images,
  - 10 - a personal computer or control computer with monitor for  
image data processing and display,
  - a tracking device for determining the momentary position of  
an instrument and for the derivation or real-time redrawing  
of representations of the patient's anatomy on the basis of  
15 the images stored in the image database, as well as
  - means for extracting anatomical structures from the raw  
data sets of the preoperative images and for making these  
structures available in the form of visualizable 3D data  
sets;
- 20 characterized by
  - a transmitter to generate a specified constant DC magnetic  
field in the navigation environment as well as a pointer  
navigation instrument with an integral magnetic-field  
sensor, such that the magnetic-field sensor and the  
25 constant-field transmitter form the tracking device and the  
magnetic-field sensor detects its own position or the  
associated position of the instrument by direction-oriented  
field-strength measurements, and
  - means for the menu-guided control of the system, wherein by  
30 movements of the pointer navigation instrument outside the  
operation field but within the navigation environment  
activate or deactivate proposed menus or control measures,  
and wherein furthermore the moment of switching is  
determined by the magnetic-field sensor's crossing a  
35 spatial distance or becoming situated at a boundary, and  
control commands are initiated or confirmed by a switch or  
key in the instrument.

- 2 -

2. Navigation system according to Claim 1,  
characterized in that by way of an image processing module of  
the personal computer a three-dimensional processing of the  
computer-tomography and nuclear-spin-tomography data from the  
5 subject is carried out, with the consequence that the data so  
obtained provide an image to be used for planning the operation  
and therapy that is identical to the findings from the  
craniotomy.
3. Navigation system according to Claim 2,  
10 characterized in that by means of the image-processing module  
anatomical structures can be selected from the complete data  
sets according to their properties or surroundings, and on the  
basis of a predeterminable segmentation strategy discrete data  
sets are produced.
- 15 4. Navigation system according to one of the preceding claims,  
characterized in that the transmitter to generate the DC  
magnetic field of the tracking device is disposed at the  
operating table or a head support provided there, but outside  
the operation field, as a result of which a fixed, reproducible  
20 positional relationship is produced between the organ of the  
patient that is to be navigated and the transmitter, regardless  
of the position of the operating table in space.
5. Navigation system according to one of the claims 2 to 4,  
characterized in that the magnetic-field sensor sends out  
25 signals from which the position and/or direction of movement of  
the pointer navigation instrument can be derived on the basis  
of the specified constant magnetic field and its orientation,  
which signals can both be displayed on the monitor and used to  
control the reloading and updating functions of the image  
30 processing module.

- 3 -

6. Navigation system according to one of the preceding claims,  
characterized in that an additional magnetic-field sensor is  
provided, such that this sensor can be attached to the subject,  
preferably to the head, in order to detect changes in location  
5 and orientation with respect to the constant-field transmitter.

7. Navigation system according to Claim 6,  
characterized in that the output signals from the second  
magnetic-field sensor are sent to the control computer as  
corrective data, in order to specify a coordinate system that  
10 is quasi-dynamic or alterable with reference to the source  
alteration.

8. Marking device or fiducial to produce image data for a  
database by means of nuclear-spin and/or computer tomography  
and to detect the position of a subject and assign coordinates  
15 for surgical operations with the assistance of a navigation  
system according to the preceding claims, comprising  
a flat carrier that can be attached to the subject by means of  
an adhesive surface as well as a contrast-marking substance  
within a container that can be separated from the carrier,  
20 characterized in that

- the carrier is constructed as an at least partially  
flexible body with a catch knob substantially centred in  
and projecting from the side away from the adhesive  
surface,
- 25 - the contrast-marking substance is contained in a housing  
that substantially comprises a hollow cylinder, such that  
the underside of the housing has a concave shape or is  
recessed and on the underside of the housing a catch  
receptacle is provided, such that object curvatures can be  
30 compensated by the shape of the underside of the housing.

9. Marking device according to Claim 8,  
characterized in that the cylindrical housing comprises a  
removable housing lid, preferably made of a transparent  
plastic, so that the marking substance can be inspected and  
5 exchanged.

10. Marking device according to Claim 8 or 9,  
characterized in that the marking substance for nuclear-spin  
tomography is a liquid or a gel, which is situated in a  
container having the form of a sphere or closed cylinder, such  
10 that the outside diameter of the sphere or cylinder corresponds  
substantially to the inside diameter of the cylindrical housing  
with catch receptacle.

11. Marking device according to one of the claims 8 to 10,  
characterized in that a closed initialization element is  
15 provided, the dimensions and underside configuration of which  
correspond to those of the cylindrical housing, such that the  
initialization element on its lid side has a marking depression  
in the same position as the middle point or centre of gravity  
of the contrast-marking substance or the spherical or  
20 cylindrical container.

12. Marking device according to one of the claims 8 to 11,  
characterized in that the cylindrical housing and the  
initialization element are made of plastic material, and the  
carrier preferably comprises a film coated on one side with  
25 adhesive.

13. Pointer for a tracking device of a navigation system for  
performing and assisting surgical operations, with an  
encapsulated sensor disposed in an elongated handpiece housing  
as well as a contact tip partially projecting out of the  
30 housing,  
characterized in that the encapsulated sensor is rigidly  
connected to the contact tip or to a receptacle for a contact

tip or insertion aid by means of an element with openings substantially opposite one another, such that the element with sensor and contact tip disposed in their respective openings is mounted quasi-cardanically so as to be yielding and stress-free with respect to the handpiece housing, and the connecting element is made of a plastic that is resistant to deformation and thermostable or of titanium.

14. Pointer according to Claim 13, characterized in that in the wall of the handpiece housing a signal key is disposed in a vapour- and liquid-tight manner.

15. Pointer according to Claim 13 or 14, characterized in that at the end of the housing opposite the contact tip, i.e. opposite the distal end of the housing, is situated a vapour- and liquid-tight cable outlet, such that the connecting element and the cable outlet are connected to the housing by external couplings.

16. Pointer according to one of the claims 13 to 15, characterized in that the connecting element is disposed with at least its sensor-receptacle opening within the housing, such that between the connecting element and the inside of the housing an annular gap is formed and to seal the gap between connecting element and housing or external coupling and housing at least one flexible sealing ring is provided.

17. Navigation system, characterized by a combination of features according to the characteristics of Claims 1 and 13.



## Abstract

5 The invention relates to a navigation system for performing and assisting surgical operations, such that the system makes use of an image database for preoperatively prepared nuclear-spin and/or computer tomography data. The system comprises means for extracting anatomical structures from the raw data sets  
10 previously obtained from the preoperative images and for making these structures available in the form of visualizable 3D data sets. The system further comprises means for generating a specified constant magnetic field in the navigation environment as well as a pointer navigation instrument with an integral  
15 magnetic-field sensor, such that the magnetic-field sensor and the constant-field transmitter form a tracking device. The system includes a menu-guided control facility, wherein by movements of the pointer navigation instrument outside the operation field but within the navigation environment, i.e. in  
20 a control field, displayed menus or control measures can be activated or deactivated. The invention also includes a special marking device or fiducial represented during the generation of image data and serving to detect the position of a subject and assign coordinates for surgical operations, as well as a  
25 pointer for the tracking device of the navigation system with a sensor specially disposed in a housing and connected to a contact tip.

Site	Procedure	Hardware	Software
MR CT	Attach markers to head Carry out MR or CT	MR or CT scanner	Operating software of the scanner
		Data transfer via local network or magneto-optical disk, CD etc.	
Labor- atory	Transfer data Segmentation 3D reconstruction	Nicolet navigation system or other PC	Windows NT IDL Navi Software
		Data transfer via local network or by bringing the already prepared Nicolet navigation system into the operating theatre	
Op. Th.	Calibration of markers on head Navigation under unsterile and sterile conditions	Nicolet navigation system	Windows NT IDL Navi Software

Fig. 1

2/9

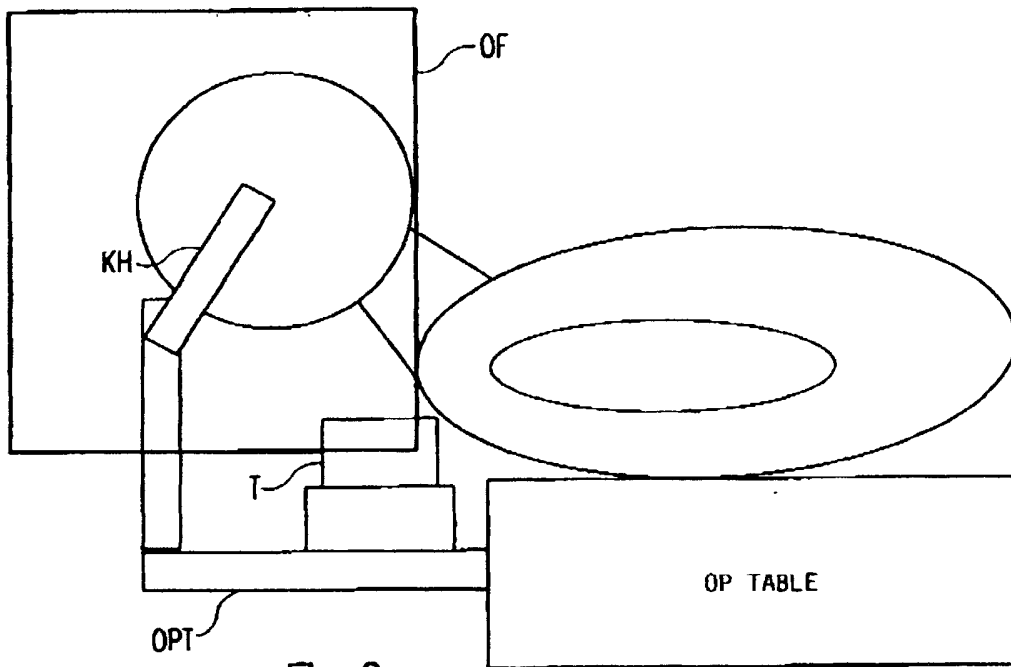


Fig. 2

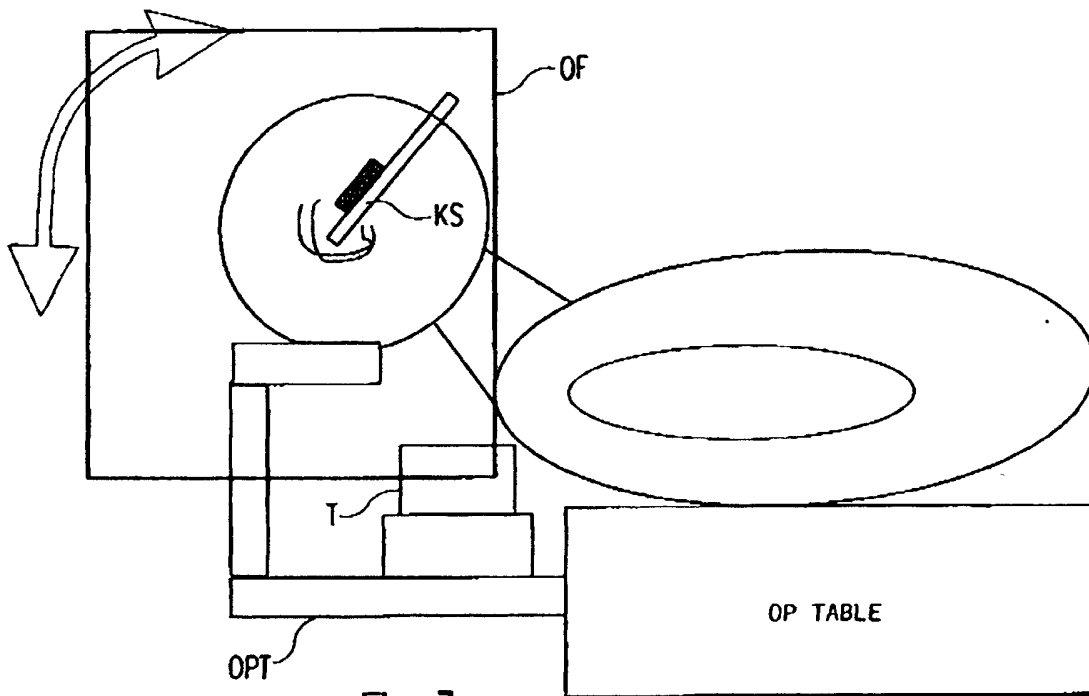


Fig. 3

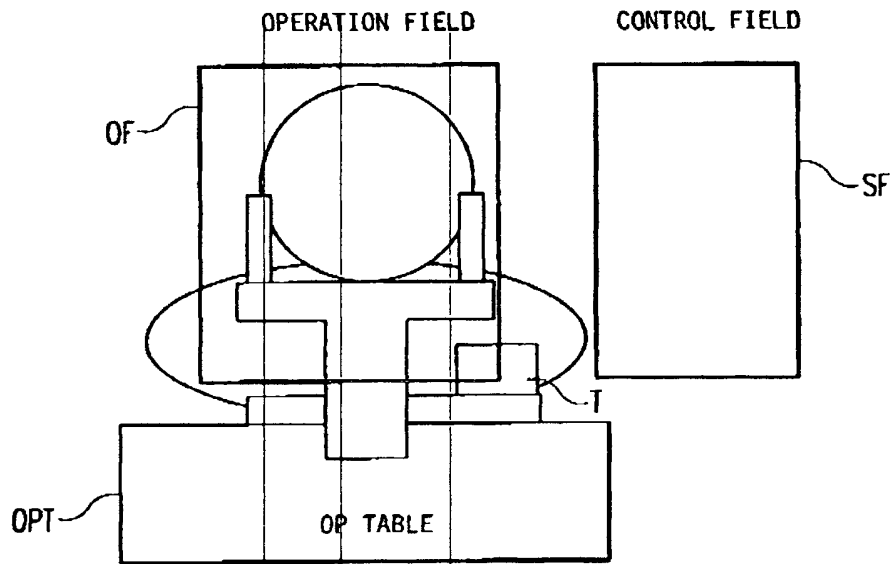


Fig. 4

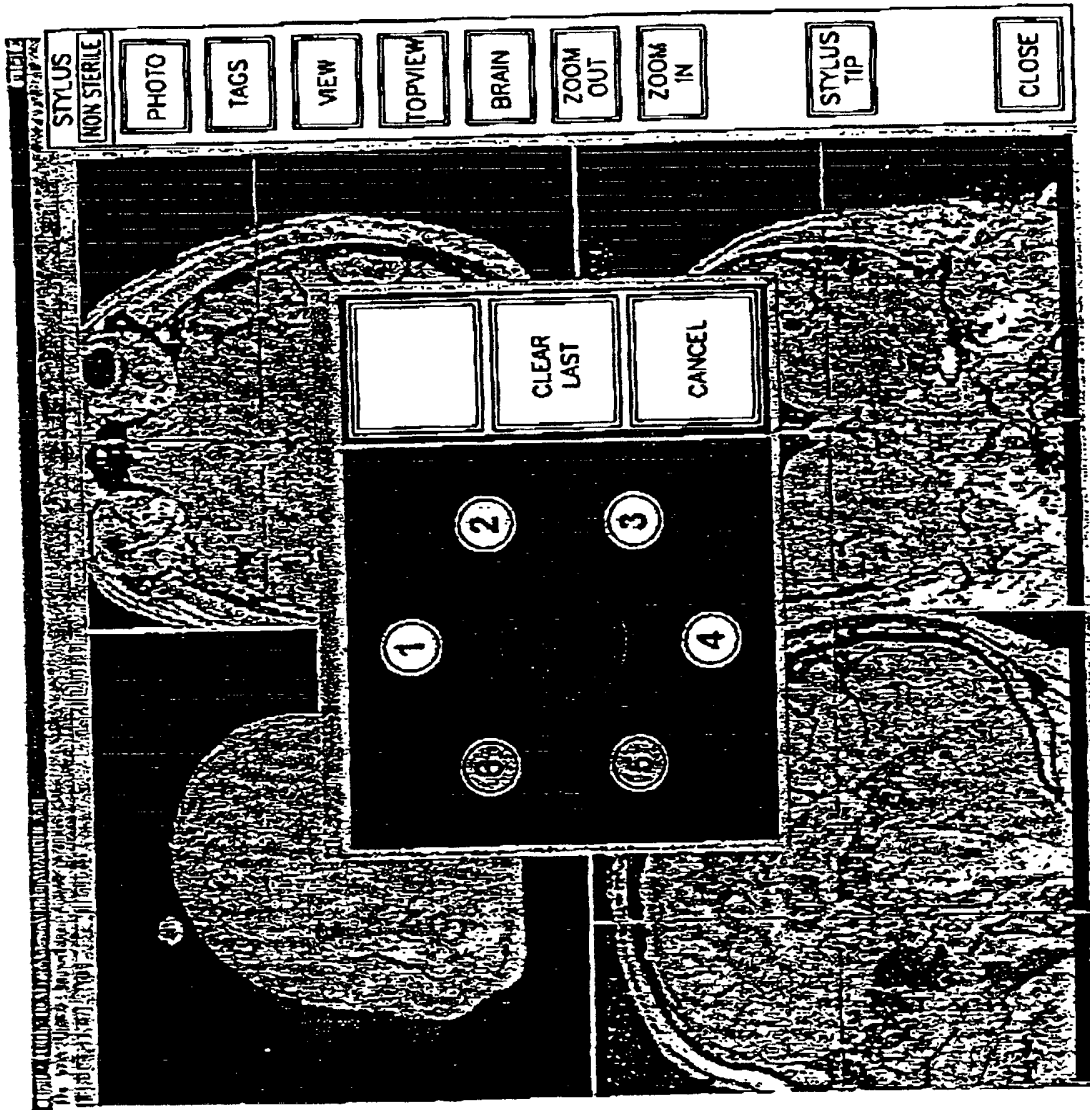


Fig. 5

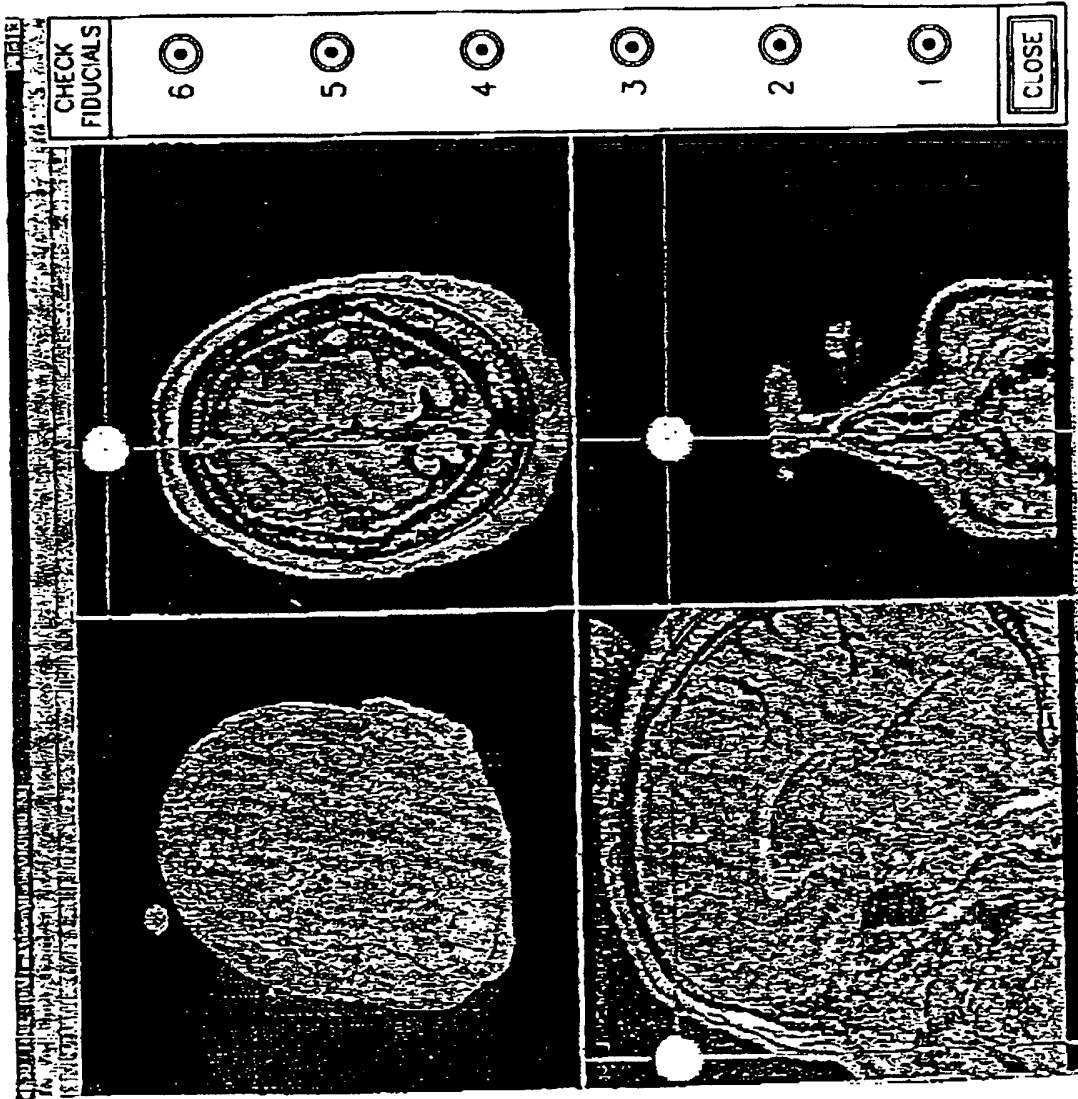


Fig. 6

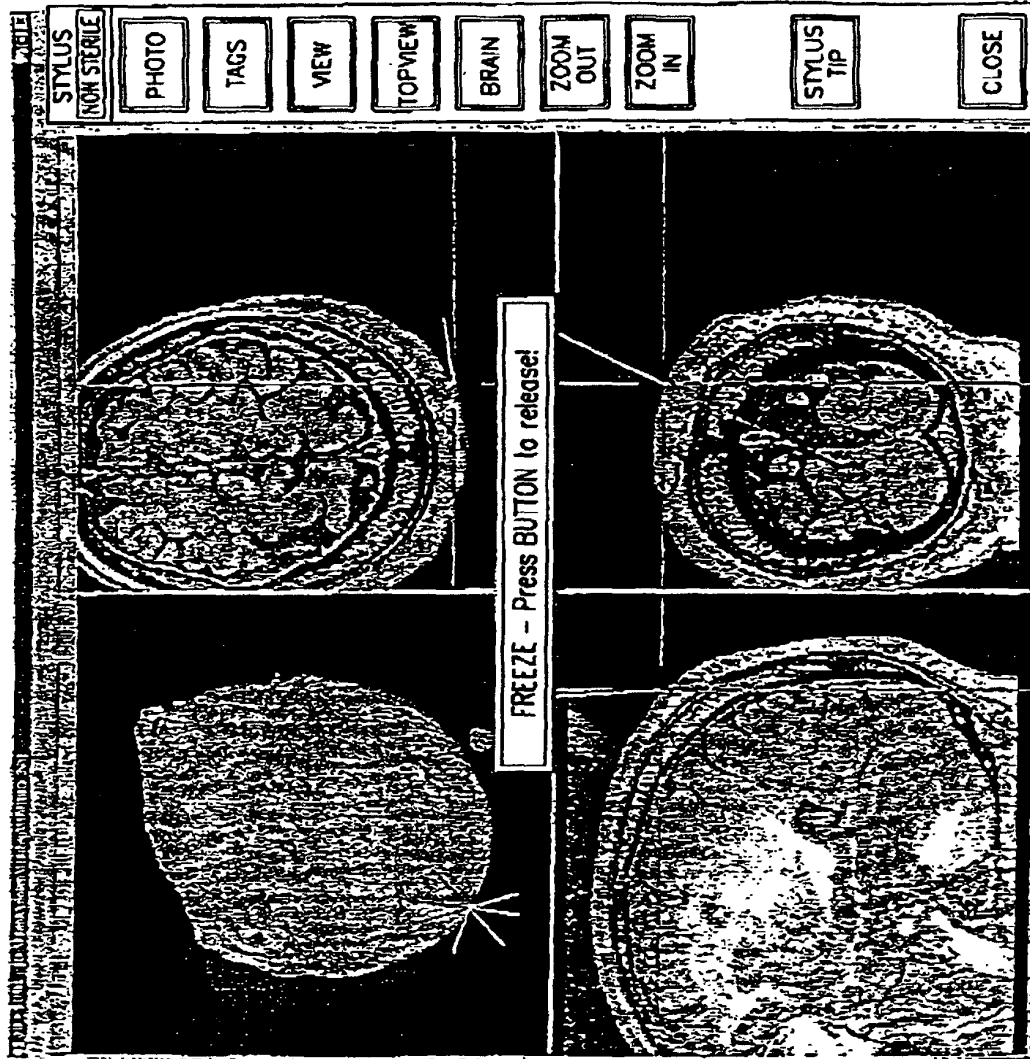


Fig. 7

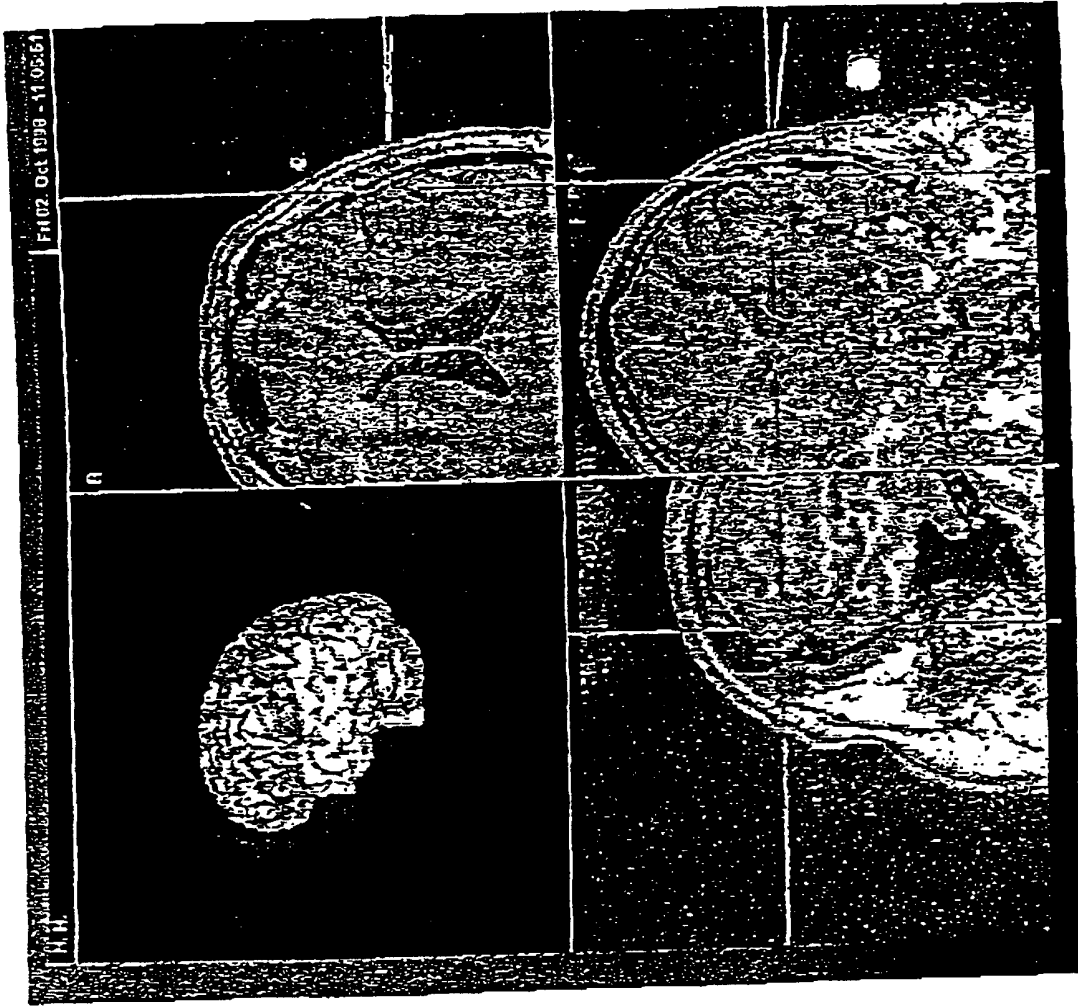


Fig. 8



8/9

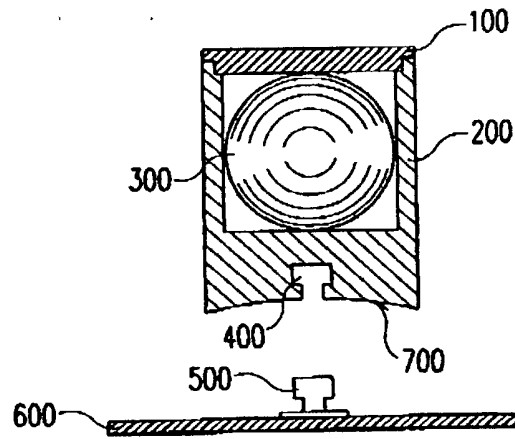


Fig. 9

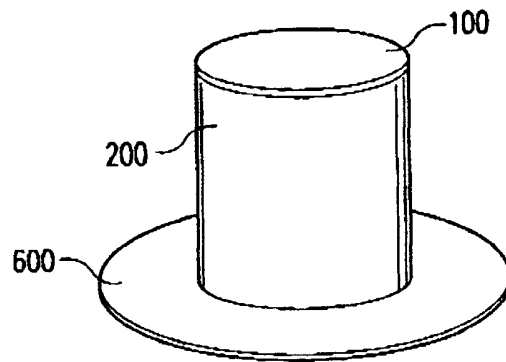


Fig. 10

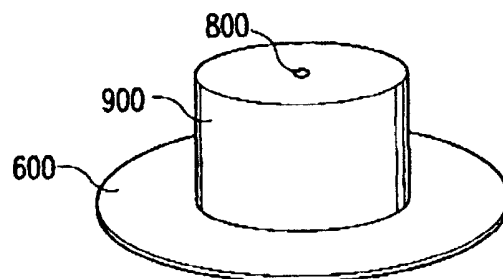


Fig. 11

9/9

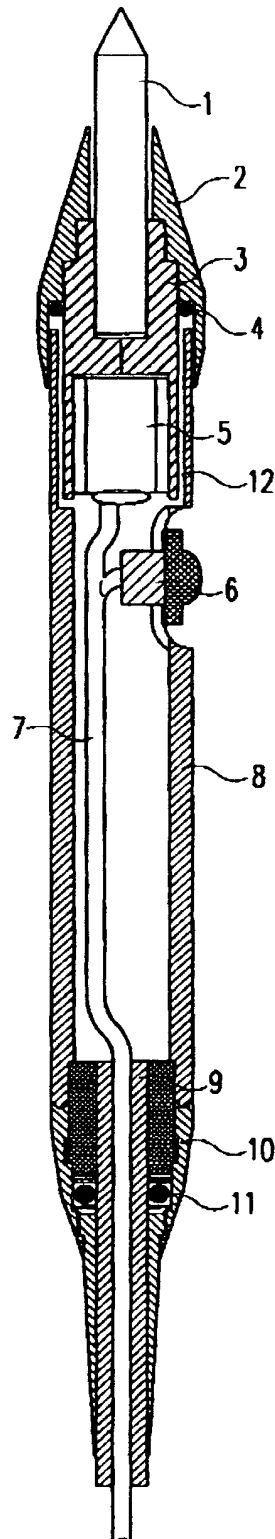


Fig. 12

Empfangen: 12.11.01 19:13;

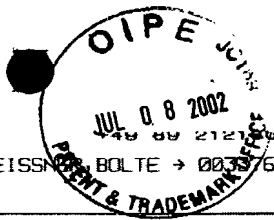
12/11/2001 18:52

MEISSNER BOLTE → 0033/62225499

09271996-013102

#6

NUM587 0004



**COMBINED DECLARATION FOR PARENT APPLICATION AND POWER OF ATTORNEY** | Attorney's Docket No. |  
(includes Reference to PCT International Applications) | MR-25 |

As a below named inventor, I hereby declare that:  
My residence, post office address and citizenship are as stated below next to my name, |

I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled: **NAVIGATION SYSTEM FOR PERFORMING AND ASSISTING SURGICAL OPERATIONS, MARKING DEVICE OR FIDUCIAL, AND POINTER FOR A TRACKING DEVICE IN A NAVIGATION SYSTEM** |

the specification of which (check only one item below):

- ☐ is attached hereto.
- ☐ was filed as United States application  
Serial No. \_\_\_\_\_  
on \_\_\_\_\_  
and was amended  
on \_\_\_\_\_ (if applicable).
- ☒ was filed as PCT international application  
Number **PCT/EP99/08602**  
on **NOVEMBER 10, 1999**  
and was amended under PCT Article 19  
on \_\_\_\_\_ (if applicable)

I hereby state that I have reviewed and understand the contents of the above-identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose information which is material to the examination of this application in accordance with Title 37, Code of Federal Regulations, §1.56(e).

I hereby claim foreign priority benefits under Title 35, United States Code, §119 of any foreign application(s) for patent or inventor's certificate or of any PCT international application(s) designating at least one country other than the United States of America listed below and have also identified below any foreign application(s) for patent or inventor's certificate or any PCT international application(s) designating at least one country other than the United States of America filed by me on the same subject matter having a filing date before that of the application(s) of which priority is claimed:

**PRIOR FOREIGN/PCT APPLICATION(S) AND ANY PRIORITY CLAIMS UNDER 35 U.S.C. 119:**

COUNTRY (if PCT, indicate PCT)	APPLICATION NUMBER (day, month, year)	DATE OF FILING UNDER 35 USC 119	PRIORITY CLAIMED YES   NO
GERMANY	198 53 010.2	17 NOVEMBER 1998	<input checked="" type="checkbox"/> YES   <input type="checkbox"/> NO
GERMANY	199 09 816.6	5 MARCH 1999	<input checked="" type="checkbox"/> YES   <input type="checkbox"/> NO


*[Signature]*  
12.11.01

Combined Declaration For Parent Application and Power of Attorney (Continued)				Docket No.	
(includes Reference to PCT International Applications)				MR-25	
I hereby claim the benefit under Title 35, United States Code, §120 of any United States application(s) or PCT international application(s) designating the United States of America that is/are listed below and, insofar as the subject matter of each of the claims of the application is not disclosed in that/those prior application(s) in the manner provided by the first paragraph of Title 35, United States Code, §112, I acknowledge the duty to disclose material information as defined in Title 37, Code of Federal Regulations, §1.56(a) which occurred between the filing date of the prior application(s) and the national or PCT international filing date of this application:					
PRIOR U.S. APPLICATIONS OR PCT INTERNATIONAL APPLICATIONS DESIGNATING THE U.S. FOR BENEFIT UNDER 35 U.S.C. 120:					
U.S. APPLICATIONS			STATUS(CHECK ONE)		
U.S. APPLICATION NUMBER	U.S. FILING DATE	PATENTED	PENDING	ABANDONED	
PCT APPLICATIONS DESIGNATING THE U.S.					
PCT APPLICATION NO.	PCT FILING DATE	U.S. SERIAL NO.			
POWER OF ATTORNEY: As a named inventor, I hereby appoint the following attorney(s) and/or agent(s) to prosecute this application and transact all business in the Patent and Trademark Office connected therewith. (List name and registration number)					
FRIEDRICH KUEFFNER, REG. NO. 29,482					
Send Correspondence to:			Direct Telephone Calls to:		
FRIEDRICH KUEFFNER 342 MADISON AVENUE, SUITE 1921 NEW YORK, N.Y. 10173			FRIEDRICH KUEFFNER (212) 886-3114		
FULL NAME		Family Name	First Given Name	Second Given Name	
2	OF INVENTOR	Hoell	Thomas		
RESIDENCE & CITY		State Or Foreign Country	Citizenship		
0	CITIZENSHIP	Halle/Saale	Germany DEX	German	
POST OFFICE ADDRESS		Post Office Address	City	State & Zip Code	
1	ADDRESS	Liebenauerstrasse 16	06110 Halle/Saale	Germany	

 J. J. J. J.  
 15.11.07

Empfangen: 12.11.07 19:14; +49 89 21218670 -> F11; Seite 6  
12/11/2001 18:52 MEISSNER, BOLTE -> 0033762225499

NUM587 0006

Combined Declaration For Parent Application and Power of Attorney (Continued)				Docket No.
(Includes Reference to PCT International Applications)				MR-25
2	FULL NAME OF INVENTOR	Family Name	First Given Name	Second Given Name
		Warschewski	Udo	
0	RESIDENCE & CITY	State Or Foreign Country	Citizenship	
	Berlin	Germany	German	
2	POST OFFICE ADDRESS	Post Office Address	City	State & Zip Code
		Dessauerstrasse 13	12249 Berlin	Germany
2	FULL NAME OF INVENTOR	Family Name	First Given Name	Second Given Name
		von Stockhausen	Hans-Martin	
0	RESIDENCE & CITY	State Or Foreign Country	Citizenship	
	Erlangen	Germany	German	
3	POST OFFICE ADDRESS	Post Office Address	City	State & Zip Code
		Hindenburgstrasse 69	91054 Erlangen	Germany
<p>I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.</p>				
SIGNATURE OF INVENTOR 201		SIGNATURE OF INVENTOR 202		SIGNATURE OF INVENTOR 203
				
DATE	DATE	DATE		
15.11.07				

 15.11.07

12/11/2001 18:52

MEISSNER, BOLTE -&gt; 0033762225499

12/11/2001 19:13 0004

**COMBINED DECLARATION FOR PARENT APPLICATION AND POWER OF ATTORNEY**  
(includes Reference to PCT International Applications)

Attorney's Docket No. |

MR-25

As a below named inventor, I hereby declare that:  
My residence, post office address and citizenship are as stated below next to my name, |

I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled: **NAVIGATION SYSTEM FOR PERFORMING AND ASSISTING SURGICAL OPERATIONS, MARKING DEVICE OR FIDUCIAL, AND POINTER FOR A TRACKING DEVICE IN A NAVIGATION SYSTEM** |

the specification of which (check only one item below):

☐ is attached hereto.☐ was filed as United States application

Serial No. \_\_\_\_\_

on \_\_\_\_\_

and was amended

on \_\_\_\_\_ (if applicable).

☒ was filed as PCT international applicationNumber **PCT/EP99/08602**on **NOVEMBER 10, 1999**

and was amended under PCT Article 19

on \_\_\_\_\_ (if applicable).

I hereby state that I have reviewed and understand the contents of the above-identified specification, including the claims, as amended by any amendment referred to above. |

I acknowledge the duty to disclose information which is material to the examination of this application in accordance with Title 37, Code of Federal Regulations, §1.56(a). |

I hereby claim foreign priority benefits under Title 35, United States Code, §119 of any foreign application(s) for patent or inventor's certificate or of any PCT international application(s) designating at least one country other than the United States of America listed below and have also identified below any foreign application(s) for patent or inventor's certificate or any PCT international application(s) designating at least one country other than the United States of America filed by me on the same subject matter having a filing date before that of the application(s) of which priority is claimed: |

**PRIOR FOREIGN/PCT APPLICATION(S) AND ANY PRIORITY CLAIMS UNDER 35 U.S.C. 119:**

COUNTRY (if PCT, indicate PCT)	APPLICATION NUMBER	DATE OF FILING (day, month, year)	PRIORITY CLAIMED UNDER 35 USC 119
-----------------------------------	--------------------	--------------------------------------	--------------------------------------

GERMANY	198 53 010.2	17 NOVEMBER 1998	<input checked="" type="checkbox"/> YES   NO
---------	--------------	------------------	--

GERMANY	199 09 816.6	5 MARCH 1999	<input checked="" type="checkbox"/> YES   NO
---------	--------------	--------------	--

12/11/2001 18:52

MEISSNER, BOLTE -&gt; 0033762225499

NUM587 0005

**Combined Declaration For Parent Application and Power of Attorney (Continued)**  
(includes Reference to PCT International Applications)

Docket No.

MR-25

I hereby claim the benefit under Title 35, United States Code, §120 of any United States application(s) or PCT international application(s) designating the United States of America that is/are listed below and, insofar as the subject matter of each of the claims of the application is not disclosed in that/those prior application(s) in the manner provided by the first paragraph of Title 35, United States Code, §112, I acknowledge the duty of disclose material information as defined in Title 37, Code of Federal Regulations, §1.56(a) which occurred between the filing date of the prior application(s) and the national or PCT international filing date of this application:

**PRIOR U.S. APPLICATIONS OR PCT INTERNATIONAL APPLICATIONS DESIGNATING THE U.S. FOR BENEFIT UNDER 35 U.S.C. 120:**

U.S. APPLICATIONS		STATUS(CHECK ONE)		
U.S. APPLICATION NUMBER	U.S. FILING DATE	PATENTED	PENDING	ABANDONED
PCT APPLICATIONS DESIGNATING THE U.S.				
PCT APPLICATION NO.	PCT FILING DATE	U.S. SERIAL NO.		

**POWER OF ATTORNEY:** As a named inventor, I hereby appoint the following attorney(s) and/or agent(s) to prosecute this application and transact all business in the Patent and Trademark Office connected therewith. (List name and registration number)

FRIEDRICH KUEFFNER, REG. NO. 29,482

Send Correspondence to:

Direct Telephone Calls to:

FRIEDRICH KUEFFNER

342 MADISON AVENUE, SUITE 1921

NEW YORK, N.Y. 10173

FRIEDRICH KUEFFNER

(212) 986-3114

	FULL NAME	Family Name	First Given Name	Second Given Name
2	OF INVENTOR	Hoell	Thomas	
	RESIDENCE & CITY	State Or Foreign Country	Citizenship	
0	CITIZENSHIP	Halle/Saale	Germany	German
	POST OFFICE ADDRESS	Post Office Address	City	State & Zip Code
1		Liebenauerstrasse 16	06110 Halle/Saale	Germany





<b>COMBINED DECLARATION FOR PARENT APPLICATION AND POWER OF ATTORNEY</b> <small>(includes Reference to PCT International Applications)</small>		Attorney's Docket No. MR-25
<p>As a below named inventor, I hereby declare that My residence, post office address and citizenship are as stated below next to my name.</p> <p>I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled: <b>NAVIGATION SYSTEM FOR PERFORMING AND ASSISTING SURGICAL OPERATIONS, MARKING DEVICE OR FIDUCIAL, AND POINTER FOR A TRACKING DEVICE IN A NAVIGATION SYSTEM</b></p> <p>the specification of which (check only one item below):</p> <p><input type="checkbox"/> is attached hereto</p> <p><input type="checkbox"/> was filed as United States application Serial No. _____ on _____ and was amended on _____ (if applicable)</p> <p><input checked="" type="checkbox"/> was filed as PCT international application Number <u>PCT/EP99/08602</u> on <u>NOVEMBER 10, 1999</u> and was amended under PCT Article 19 on _____ (if applicable).</p> <p>I hereby state that I have reviewed and understand the contents of the above-identified specification, including the claims, as amended by any amendment referred to above.</p> <p>I acknowledge the duty to disclose information which is material to the examination of this application in accordance with Title 37, Code of Federal Regulations, §1.56(a).</p> <p>I hereby claim foreign priority benefits under Title 35, United States Code, §119 of any foreign application(s) for patent or inventor's certificate or of any PCT international application(s) designating at least one country other than the United States of America listed below and have also identified below any foreign application(s) for patent or inventor's certificate or any PCT international application(s) designating at least one country other than the United States of America filed by me on the same subject matter having a filing date before that of the application(s) of which priority is claimed:</p>		
<b>PRIOR FOREIGN/PCT APPLICATION(S) AND ANY PRIORITY CLAIMS UNDER 35 U.S.C. 119:</b>		
COUNTRY <small>(if PCT, indicate PCT)</small>	APPLICATION NUMBER <small>(day, month, year)</small>	DATE OF FILING <small>(day, month, year)</small>
GERMANY	199 63 810.2	17 NOVEMBER 1998
GERMANY	199 09 816.6	5 MARCH 1999
PRIORITY CLAIMED <small>UNDER 35 USC 119</small>		
<div style="display: flex; justify-content: space-between;"> <span><input checked="" type="checkbox"/> YES</span> <span><input type="checkbox"/> NO</span> </div>		

Combined Declaration for Parent Application and Power of Attorney (Continued)				Docket No.	
(includes Reference to PCT International Applications)				MR-25	
<p>I hereby claim the benefit under Title 35, United States Code, §120 of any United States application(s) or PCT international application(s) designating the United States of America that is/are listed below and, insofar as the subject matter of each of the claims of the application is not disclosed in that/those prior application(s) in the manner provided by the first paragraph of Title 35, United States Code, §112, I acknowledge the duty to disclose material information as defined in Title 37, Code of Federal Regulations, §1.56(a) which occurred between the filing date of the prior application(s) and the national or PCT international filing date of this application:</p>					
PRIOR U.S. APPLICATIONS OR PCT INTERNATIONAL APPLICATIONS DESIGNATING THE U.S. FOR BENEFIT UNDER 35 U.S.C. 120:					
U.S. APPLICATIONS			STATUS (CHECK ONE)		
U.S. APPLICATION NUMBER	U.S. FILING DATE	PATENTED	PENDING	ABANDONED	
PCT APPLICATIONS DESIGNATING THE U.S.					
PCT APPLICATION NO.	PCT FILING DATE	U.S. SERIAL NO.			
POWER OF ATTORNEY: As a named inventor, I hereby appoint the following attorney(s) and/or agent(s) to prosecute this application and transact all business in the Patent and Trademark Office connected therewith. (List name and registration number)					
FRIEDRICH KUEFFNER, REG. NO. 29,482					
Send Correspondence to:			Direct Telephone Calls to:		
FRIEDRICH KUEFFNER 342 MADISON AVENUE, SUITE 1021 NEW YORK, N.Y. 10173			FRIEDRICH KUEFFNER (212) 986-3714		
FULL NAME: Family Name First Given Name Second Given Name					
2	OF INVENTOR	Host	Thomas		
RESIDENCE & City State Or Foreign Country Citizenship					
0	CITIZENSHIP	Halle/Saale	Germany	German	
1 POST OFFICE Post Office Address City State & Zip Code					
	ADDRESS	Liebenauerstrasse 10	06110 Halle/Saale	Germany	

Empfangen: 12.11.01 19:14:

+49 89 21218670 -> FII; Seite 8

12/11/2001 18:52

MEISSNER.BOLTE -> 0033762225499

NUM587 0006

3-00

**Combined Declaration For Parent Application and Power of Attorney (Continued)** | Docket No. |  
(Includes Reference to PCT International Applications) | MR-25 |

FULL NAME   Family Name   First Given Name   Second Given Name	
2   OF INVENTOR	Werschewake   Udo
RESIDENCE & City   State Or Foreign Country   Citizenship	
0   CITIZENSHIP	Berlin   Germany   German
POST OFFICE   Post Office Address   City   State & Zip Code	
2   ADDRESS	Dessauerstrasse 13   12249 Berlin   Germany

FULL NAME   Family Name   First Given Name   Second Given Name	
2   OF INVENTOR	von Stockhausen   Hans-Martin
RESIDENCE & City   State Or Foreign Country   Citizenship	
0   CITIZENSHIP	Erlangen   Germany DEX   German
POST OFFICE   Post Office Address   City   State & Zip Code	
3   ADDRESS	Hindenburgstrasse 89   91054 Erlangen   Germany

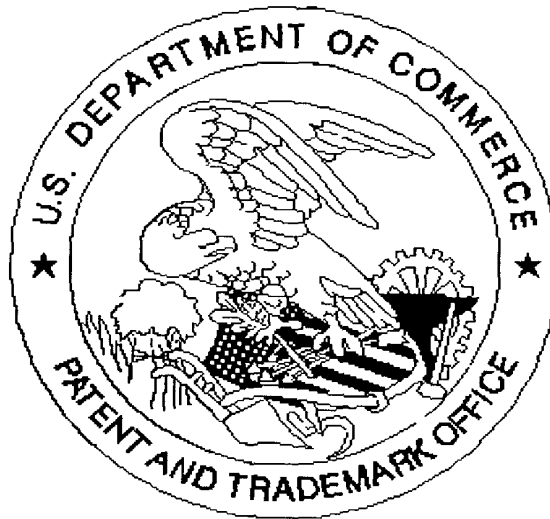
I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

SIGNATURE OF INVENTOR 201 | SIGNATURE OF INVENTOR 202 | SIGNATURE OF INVENTOR 203 |

DATE | DATE | DATE |

14/11/2001

United States Patent & Trademark Office  
Office of Initial Patent Examination -- Scanning Division



Application deficiencies found during scanning:

☐ Page(s) \_\_\_\_\_ of \_\_\_\_\_ were not present  
for scanning. (Document title)

☐ Page(s) \_\_\_\_\_ of \_\_\_\_\_ were not present  
for scanning. (Document title)

☐ *Scanned copy is best available drawing all dark*